

Patent Case: OC01000KQ

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Application of: Rybak *et al.* :  
For: MELANOMA THERAPY : Group Art Unit: 1642  
Serial No.: TBD :  
Filed: July 12, 2001 : Examiner: Holleran, A.  
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Assistant Commissioner for Patents  
Washington, D.C. 20231



**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the applicants' duty of disclosure expressed in 37 C.F.R. § 1.56, the examiner's attention is directed to the documents listed on the accompanying form PTO-1449. Copies of these references were provided in the parent application. New copies are available on request.

The Examiner should be aware of U.S.S.N 09/288,366 filed April 8, 1999, now abandoned, which discloses similar subject matter.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

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July 12, 2001  
Date of Deposit

\_\_\_\_\_  
Donald W. Wyatt  
Registered Representative

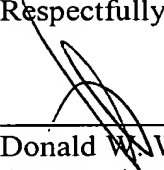
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July 12, 2001  
Date of Signature

Consideration of each document, and the return of an initialed copy of the form PTO-1449 to indicate such consideration, are respectfully requested.

Respectfully submitted,

Date: July 12, 2001



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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: OCO1000KQ	SERIAL NO.:
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use several sheets if necessary)</i>		APPLICANT: Rybak et al.	
		FILING DATE: July 11, 2001	GROUP: 1642

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,985,263	11/16/99	Lee et al.	424	85.2	
	AB	5,951,974	09/14/99	Gilbert et al.	424	85.7	
	AC	5,908,621	06/01/99	Chue et al.	424	85.7	
	AD	4,766,106	08/23/88	Katre et al.	514	12	
	AE	5,776,897	07/07/98	Lewis et al.	514	12	
	AF	5,766,582	06/18/98	Yuen et al.	424	85.7	
	AG	5,762,923	06/09/98	Gross et al.	424	85.7	
	AH	5,382,427	01/17/95	Plunkett et al.	424	85.2	
	AI	4,917,888	04/17/90	Katre et al.	424	85.91	
	AJ	4,897,471	01/30/90	Stabinsky	536	27	
	AK	4,695,623	09/22/87	Stabinsky	530	351	
	AL	4,530,901	07/23/85	Weissmann	435	70	
	AM	4,492,537	01/08/85	Awerkamp	417	404	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES	NO
	AN	0 236 987 B1	12/28/94	EPO				
	AO	0 809 996 A2	12/03/97	EPO				
	AP	0 593 868 A1	04/27/94	EPO				
	AQ	WO 99/48535	30/09/99	WIPO				
	AR	0 510 356 A1	10/28/92	EPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AS	Kantarjian et al., "Treatment of Chronic Myelogenous Leukemia: Current Status and Investigational Options," Blood <b>87</b> :8 pp. 3069-3081, April 15, 1996
AT	Hehlman et al., "Randomized Comparison of Interferon- $\alpha$ With Busulfan and Hydroxyurea in Chronic Myelogenous Leukemia," Blood <b>84</b> :12 pp. 4064-4077, December 15, 1994
AU	Kantarjian et al., "Chronic Myelogenous Leukemia: A Concise Update," Blood <b>82</b> :3 pp. 691-703, August 1, 1993
AV	Nicolaou et al., "Total Synthesis of Taxol. 1. Retrosynthesis, Degradation, and Reconstitution," J. Am. Chem. Soc. <b>117</b> pp. 624-633, 1995
AW	Hasford, et al "Interferon- $\alpha$ and Hydroxyurea in Early Chronic Myeloid Leukemia: A Comparative Analysis of the Italian and German Chronic Myeloid Leukemia Trials With Interferon- $\alpha$ ,"
AX	Ozer et al., "Prolonged Subcutaneous Administration of Recombinant $\alpha$ 2b Interferon in Patients with Previously Untreated Philadelphia Chromosome-Positive Chronic-Phase Chronic Myelogenous Leukemia: Effect on Remission Duration and Survival: Cancer and Leukemia Group B Study 8583," Blood <b>82</b> :10 pp. 2975-2984, November 15, 1993
AY	Ohnishi et al., "A Randomized Trial Comparing Interferon- $\alpha$ With Busulfan for Newly Diagnosed Chronic Myelogenous Leukemia in Chronic Phase," Blood <b>86</b> :3 pp. 906-916, August 1, 1995
AZ	Creagon et al., "Randomized, Surgical Adjuvant Clinical Trial of Recombinant Interferon Alfa-2a in Selected Patients With Malignant Melanoma," Journal of Clinical Oncology, <b>13</b> :13 pp. 2776-2783 November 1995
BA	Bergmann et al., "Daily Alternating Administration of High-Dose Alpha-2b-Interferon and Interleukin-2 Bolus Infusion in Metastatic Renal Cell Cancer," Cancer <b>72</b> :5, pp. 1735-1742 September 1, 1993
BB	Umeda et al., "Phase II Study of Alpha Interferon on Renal Cell Carcinoma," Cancer <b>58</b> :1231-1235, September 15, 1986

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BC	Sokal et al., "Preferential Inhibition by Cytarabine of CFU-GM From Patients With Chronic Granulocytic Leukemia," <i>Cancer</i> <b>59</b> :197-202, January 1, 1987
BD	Fleming et al., "One-Sample Multiple Testing Procedure for Phase II Clinical Trials," <i>Biometrics</i> <b>38</b> :143-151 March 1982
BE	Rosenberg, et al., "Experience with the Use of High-Dose Interleukin-2 in the Treatment of 652 Cancer Patients," <i>Ann. Surg.</i> <b>210</b> :4 pp. 474-485, 1989
BF	Kantarjian et al., "Prolonged Survival in Chronic Myelogenous Leukemia after Cytogenetic Response to Interferon- $\alpha$ Therapy," <i>Ann Intern Med.</i> <b>122</b> :254-261, 1995
BG	Talpaz et al., "Interferon-Alpha Produces Sustained Cytogenetic Responses in Chronic Myelogenous Leukemia," <i>Annals of Internal Medicine</i> , <b>114</b> :7 April 1, 1991
BH	Négrier et al., "Intensive Regimen of Cytokines with Interleukin-2 and Interferon Alfa-2B in Selected Patients with Metastatic Renal Carcinoma," <i>Journal of Immunotherapy</i> , <b>17</b> :62-68 1995
BI	Goldman, "Optimizing Treatment for Chronic Myeloid Leukemia," <i>The New England Journal of Medicine</i> , <b>337</b> :4, pp. 270-271, July 24, 1997
BJ	Guilhot, et al., "Interferon Alfa-2b Combined with Cytarabine Versus Interferon Alone in Chronic Myelogenous Leukemia," <i>The New England Journal of Medicine</i> , <b>337</b> :4 pp. 223-229
BK	The Italian Cooperative Study Group on Chronic Myeloid Leukemia, "Interferon Alfa-2a as Compared with Conventional Chemotherapy for the Treatment of Chronic Myeloid Leukemia," <i>The New England Journal of Medicine</i> , <b>330</b> :12 pp.820-825, March 24, 1994
BL	Atzpodien et al., "Multinstitutional Home-Therapy Trial of Recombinant Human Interleukin-2 and Interferon Alfa-2 in Progressive Metastatic Renal Cell Carcinoma," <i>Journal of Clinical Oncology</i> , <b>13</b> :2 pp. 497-501 February 1995
BM	Kirkwood et al., "Interferon Alfa-2b Adjuvant Therapy of High-Risk Resected Cutaneous Melanoma: The Eastern Cooperative Oncology Group Trial EST 1684," <i>Journal of Clinical Oncology</i> , <b>14</b> :1 pp. 7-17, January 1996
BN	Atzpodien et al., "Home therapy with recombinant interleukin-2 and interferon- $\alpha$ 2b in advanced human malignancies," <i>The Lancet</i> , <b>335</b> pp. 1509-1512, 1990
BO	Alfonso Gennaro, "Antineoplastic and Immunoactive Drugs," Remington's 18 <sup>th</sup> Ed., 1990
BP	Bukowski, "Phase 1 Study of Polyethylene Glycol (PEG) Interferon Alpha-2B (PEG INTRON) in Patients with Solid Tumors," <i>American Society of Clinical Oncology</i> , 1999 Abstract
BQ	Cascinelli, N. et al., "Results of adjuvant interferon study in WHO melanoma programme," <i>The Lancet</i> , <b>343</b> :913-914 April 9, 1994
BR	<del>American Society of Clinical Oncology, 15 May 1996, Abstract #628, p. 298</del>
BS	<del>P. Sagaster et al., "Randomised Study Using IFN-<math>\alpha</math> versus IFN-<math>\alpha</math> plus coumarin and cimetidine for treatment of advanced renal cell cancer," <i>Annals of Oncology</i> <b>6</b>:999-1003, 1995</del>
BT	<del>D. Osoba, et al., "Modification of the EORTC QLQ-C30 (version 2.0) based on content validity and reliability testing in large samples of patients with cancer," <i>Quality of Life Research</i> <b>6</b>:103-108, 1997</del>
BU	Sewa S. Legha, "The Role of Interferon Alfa in the Treatment of Metastatic Melanoma," <i>Seminars in Oncology</i> , <b>24</b> :1 Suppl 4 (February) 1997, pp. S4-24-S4-31
BV	W. Levens et al., "Long-Term Interferon Treatment in Metastatic Renal Cell Carcinoma," <i>Eur Urol.</i> <b>16</b> :378-381, 1989
BW	Janice P. Dutcher, et al., "Outpatient Subcutaneous Interleukin-2 and Interferon-Alpha for Metastatic Renal Cell Cancer: Five-Year Follow-up of the Cytokine Working Group Study," <i>The Cancer Journal from Scientific American</i> <b>3</b> :3 May/June 1997
BX	Talpaz et al., "Phase I Study Of Polyethylene Glycol (PEG) Interferon Alpha-2B (Intron-A) in CML Patients", <i>Blood</i> , Volume 92, Issue 10, Suppl. 1 part 1-2, 11/15, 1998, pp. 251A
BY	Talpaz et al., "Phase I Study Of Pegylated-Interferon $\alpha$ -2A (PEGASYS™) In Patients With Chronic Myelogenous Leukemia (CML)", <i>Blood</i> , Vol. 94, Issue 10, Suppl. 1, part 1, 11/15, 1999, pp.530A.
BZ	Walther P.J. et al., "Treatment of Metastatic Renal Cell Carcinoma (RCC) with Continuous Infusion of Fluorouracil and Interferon Alpha-2A in the Home Setting: A Phase I-II Trial", <i>Proceedings of the American Urological Association</i> , Vol. 155, May 1996 Supplement, p. 388A.

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<input checked="" type="checkbox"/>	CA	Gebrosky et al., "Treatment of Renal Cell Carcinoma with 5-Fluorouracil and Alfa-Interferon", <i>Urology</i> , 50 (6) 1997, pp. 863-868.
	<input checked="" type="checkbox"/>	CB

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.